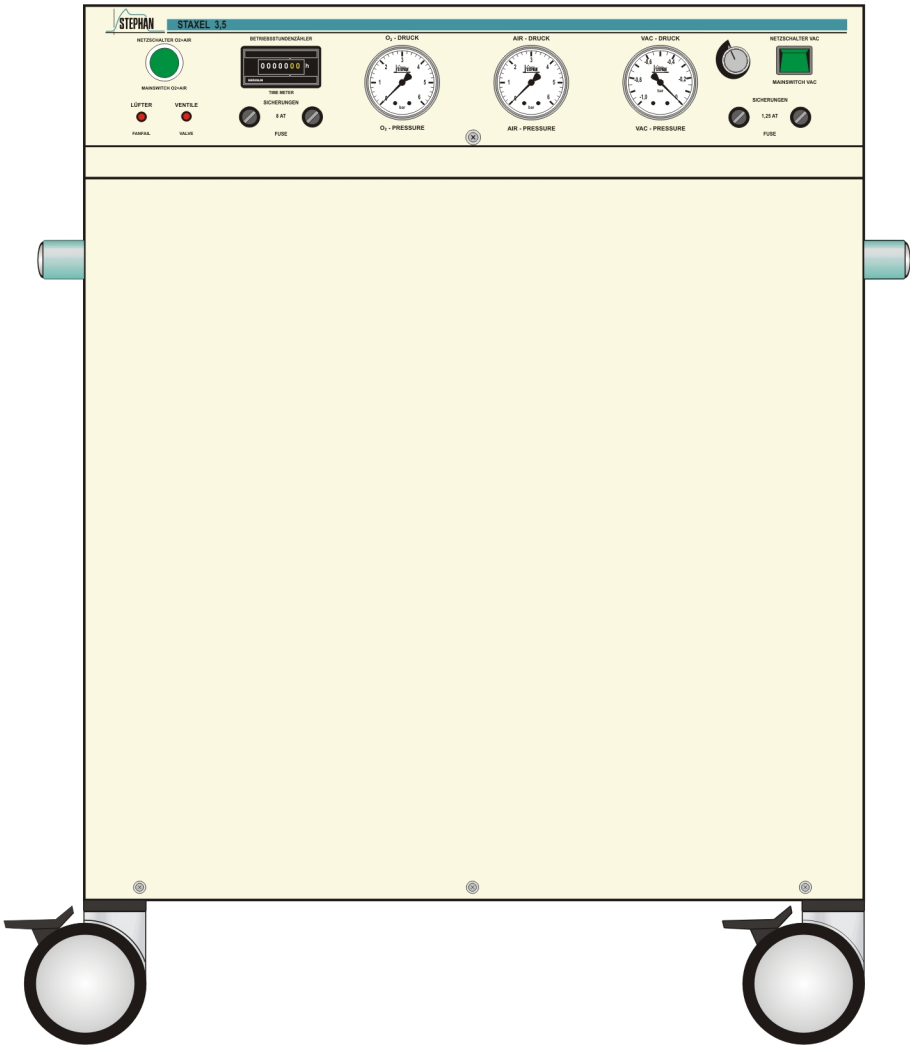
STEPHAN

Clinical Experience
Technical Competence

Staxel 3.5

O_2 AIR Energy Supply Module



Operating Manual

CE 0482

Operating manual

This operating manual intends to provide clear answers to any questions about how to use and care for **STAXEL 3.5**.

This operating manual does not contain any instructions for repairs and installation.

In the event of any faults during operation, please contact the authorized customer service of F. STEPHAN GMBH or the authorized dealer who delivered the device to you and provided you with the initial instructions on how the device functions and how to operate it.

The manufacturer only warrants the safety and reliability of **STAXEL 3.5**, if it is operated in conformity with the operating manual.

F. Stephan GmbH
- Medizintechnik -
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Subject to technical alterations.

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1 General information

1.1 Product combination

Combinations with other products can impair the performance and safety of **STAXEL 3.5**.

F. STEPHAN GMBH rules out any warranty for unacceptable device combinations operating with products not approved by the manufacturer or products without certified compatibility.

Only use the accessories stated in chapter 9 on page 35.

1.2 Device name and manufacturer

Device name **STAXEL 3.5**

Manufacturer

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1.3 Proper use

Oxygen concentrators provide a safe source of oxygenated air for patients needing it. These devices increase the level of oxygen by filtering out the nitrogen from the ambient air.

STAXEL 3.5 constantly generates oxygen from the ambient air and offers an economic alternative to bottled or liquid oxygen.

STAXEL 3.5 is used to generate oxygen and to produce compressed air and vacuum; it is designed primarily for operating ventilation and anesthesia systems.

Other combinations are also available on request or order.

1.4 Packaging and waste disposal

Packaging

The device packaging consists essentially of recyclable or reusable materials.

The carton packaging can be reused or disposed of as used paper.

The wrapping consists of CFC-free padding which can be disposed of together with the foil as recyclable plastic waste (in Germany: yellow trash can).

Return/disposal

F. STEPHAN GMBH guarantees that used devices from our company can be returned free of charge and disposed of correctly, thus making a contribution to the environment.

1.5 Introduction

German legislation

The Medical Devices Law (MPG), the Medical Devices Operator Ordinance (MPBetreibV) and the Law on Technical Working Equipment stipulate that the operator's attention must be drawn to the following:

- The device must only be operated by skilled staff who must have an exact knowledge of the operating manual.
- Only use the device for the intended purpose described in the operating manual.
- Read the operating manual through carefully and comply with its instructions, because lasting safety for patient and user is only warranted when the device is operated perfectly.
- The operating manual must be kept constantly available at the place of use.
- Faulty care and operation can cause work stoppages and accidents.

Warranty

The manufacturer does not accept any warranty claims resulting from incorrect operation or inadequate care and maintenance.

The manufacturer only guarantees the safety and reliability of the device if it is operated in compliance with the operating manual.

1.6 Abbreviations and definitions

Abbrevations	Definition	Meaning
AIR		Medical compresed air
bar		Unit of measurement for compressed air
DIN		German standardization institute
EN		European standard
Flow		Volume flow
LED		Light Emitting Diode
min	minutes	Unit of time
O_2		Oxygen
OG		Upper limit
s	seconds	Unit of time
UG		Lower limit
VAC		Vacuum

Tab. 1: Abreviations and definitions

1.7 Technical data

Ambient conditions

Operation	Temperature	15 – 40 °C
	Rel. humidity	30 – 85 %
	Air pressure	900 – 1060 hPa
	Bring to room temperature before starting to operate the device.	
Storage	Temperature	5 – 60 °C
	Rel. humidity	10 – 100 %
	Air pressure	700 – 1060 hPa
	Store in a protected, dust-free place protected from moisture and frost	

General

MPG class	II b
Protection class	I type B as per DIN EN 60601-1 :March 1996
Inspection/maintenance cycle	annual
Dimensions (WxHxD)	610 x 820 x 680 mm
Weight	122 kg

Power supply

Mains	Connection	230 V AC 50 – 60 Hz
	Input power	6 A
	Device fuses	2 x 8 AT
		2 x 1.25 AT

Specifications

Absorber unit	Pressure	2.2 bar
	Changeover cycle	11 s
	Flushing time	2 s

	O_2	**AIR**
System pressure	5.2 bar	5.2 bar
Output pressure	3.8 bar	3.8 bar
Consumption	6 l/min	8 l/min
Max. consumption	7 l/min	13 l/min

Compressed air compressor

Voltage	230 V / 50 Hz
Motor speed/output	1350 rpm / 435 Watt
Capacitor	15 µF

Compressor for post-compression

Voltage	230 V / 50 Hz
Motor speed/output	1390 rpm / 435 Watt
Capacitor	15 µF

Flat fan

Voltage	230 V / 50 Hz
Motor speed	2800 rpm
Input power	45 VA
Noise level	48 dB
Dimensions	150 ∅ x 55 mm

Parameters

Pressure gauge	O_2	0 – 6 bar
	AIR	0 – 6 bar
	VAC	-1 – 0 bar

O_2 concentration

Flow [l/min]	**O_2 concentration [%]**
1 – 2	95
3 – 6	94
7	90
8	88
9	80

Tab. 2: Available O_2 concentration at corresponding flow

Monitoring

Parameter	**Unit**	**UG**	**OG**
Pressure sensor	bar	2.5	5.5
Temperature sensor	°C		45
Pressure relief valve	bar		5,5

Tab. 3: Alarm limits

Alarm	visual, acoustic

2 Safety instructions

Refers to instructions drawing attention to important facts.

The following safety instructions are repeated at relevant points in the operating manual and must always be heeded.

Danger

Refers to dangers which, if not heeded, can result in life-threatening injuries to the patient and/or operator.

Warning

Refers to warnings which, if not heeded, can result in malfunctions, damage or defects in the device, which can possibly also put the patient at danger.

Caution

Refers to precautions which, if not heeded, can result in damage to the device and its accessories.

2.1 Danger warnings

Danger

The device must be operated according to the instructions in this operating manual.

Danger

STAXEL 3.5 is not certified for use in explosion-risk areas.

Danger

STAXEL 3.5 must not be operated in the vicinity of naked flames or glowing objects, given the increased explosion risk from the concentration of pure oxygen in the device.

Danger

The device must not be used when damaged. Disconnect from the mains.

Danger

Always disconnect the device from the mains immediately in any dangerous situations or when technical faults occur.

2.2 Warnings

Warning

When moving the device, ensure that the wheel brakes have been released and are applied again when set upright.

Warning

DIN EN 60601-1 resp. VDEO 0751-1 must be heeded in particular for medical technical devices with electrical connection. Accordingly, these devices must only be repaired by the manufacturer or an entity explicitly authorized for this purpose by the manufacturer.

Warning

The provisions of DIN EN 60601-1 must be heeded when connecting external electrical devices.

Warning

Only the authorized customer service of F. STEPHAN GMBH is allowed to alter, modify, repair or open the device. This also includes replacing the bacteria filter, intake filter and intake filter mat in accordance with the operating manual. Use only spare parts from F. STEPHAN GMBH for maintenance.

3 Structure and description of functions

3.1 Front view

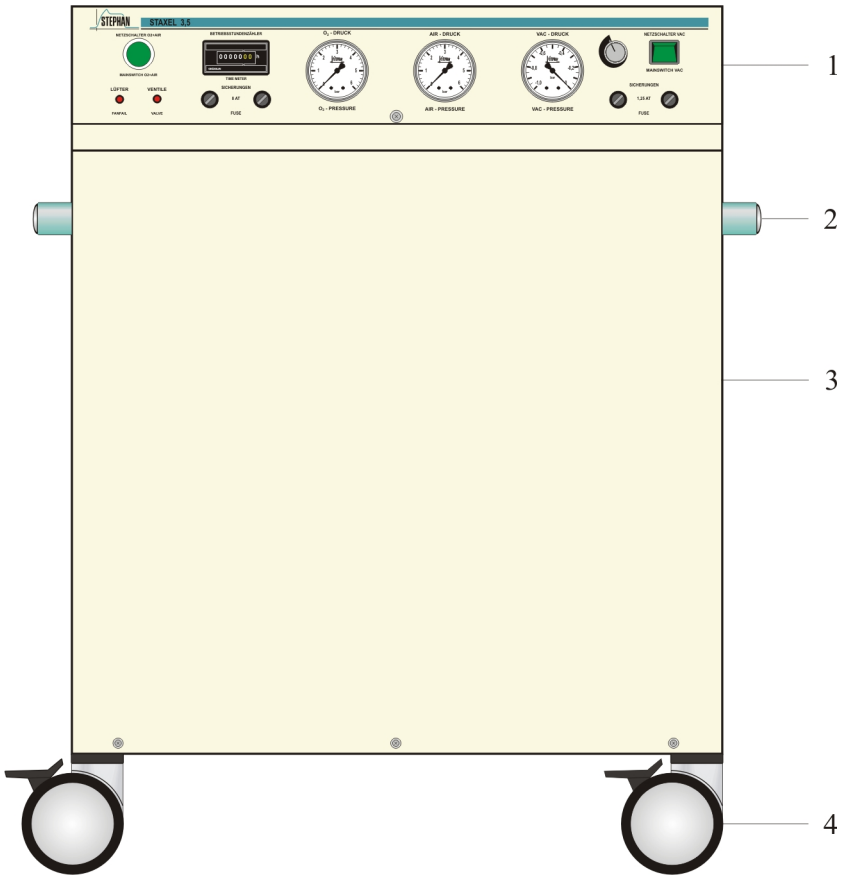

Fig. 1: Front view

1	Controls and display elements	3	Housing jacket
2	Handles	4	Rollers (4, 2 can be fixed)

3.2 Controls and display elements

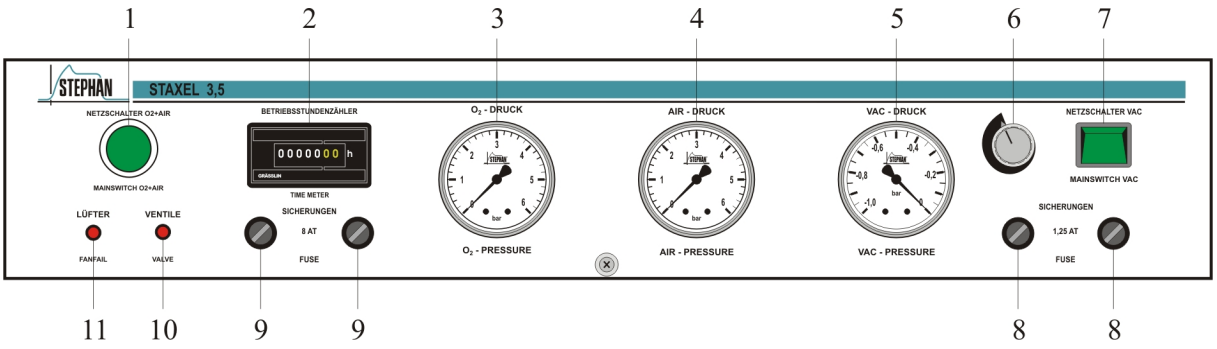

Fig. 2: Controls and display elements

1 Mains switch "On/Off" for O_2 and AIR
2 Operating hours counter for O_2 and AIR generation
3 Pressure gauge for O_2 pressure display
4 Pressure gauge for AIR pressure display
5 Pressure gauge for VAC pressure display
6 Knob for regulating the vacuum
7 Mains switch "On/Off" for VAC
8 Fuse for VAC generation
9 Fuse for O_2 and AIR generation
10 Visual alarm for failure of electronic components or switching valves
11 Visual alarm for overheating

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3.3 Rear view

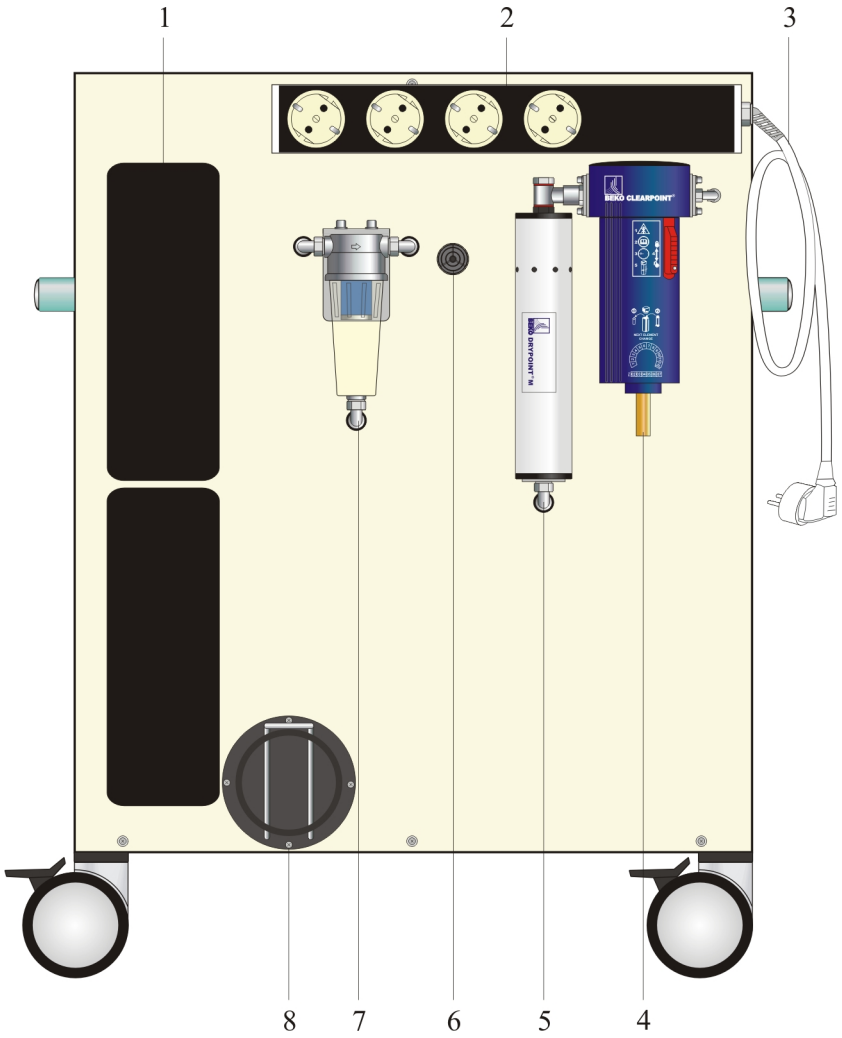

Fig. 3: Rear view

1	Intake filter mat	5	Membrane dryer
2	Power sockets (230 V AC)	6	Acoustic alarm
3	Connection lead	7	Water separator
4	Filter	8	Filter unit

3.4 Right-hand side view

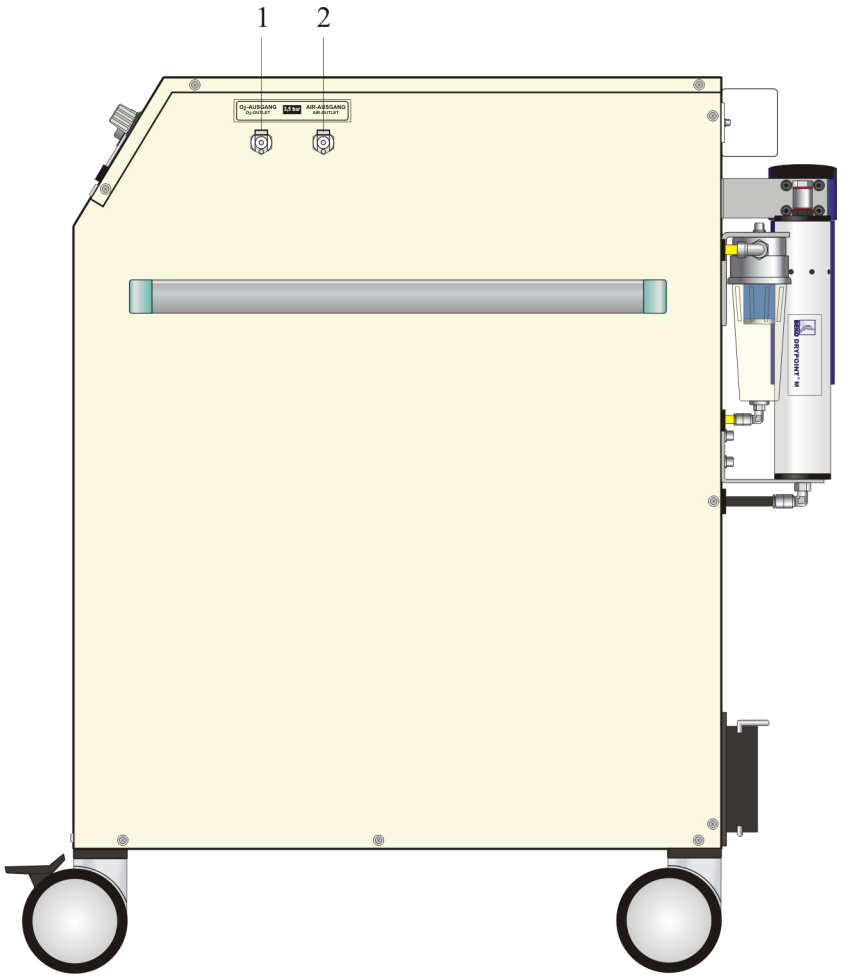

Fig. 4: Right-hand side view

1 O_2 outlet

2 AIR outlet

3.5 Left-hand side view

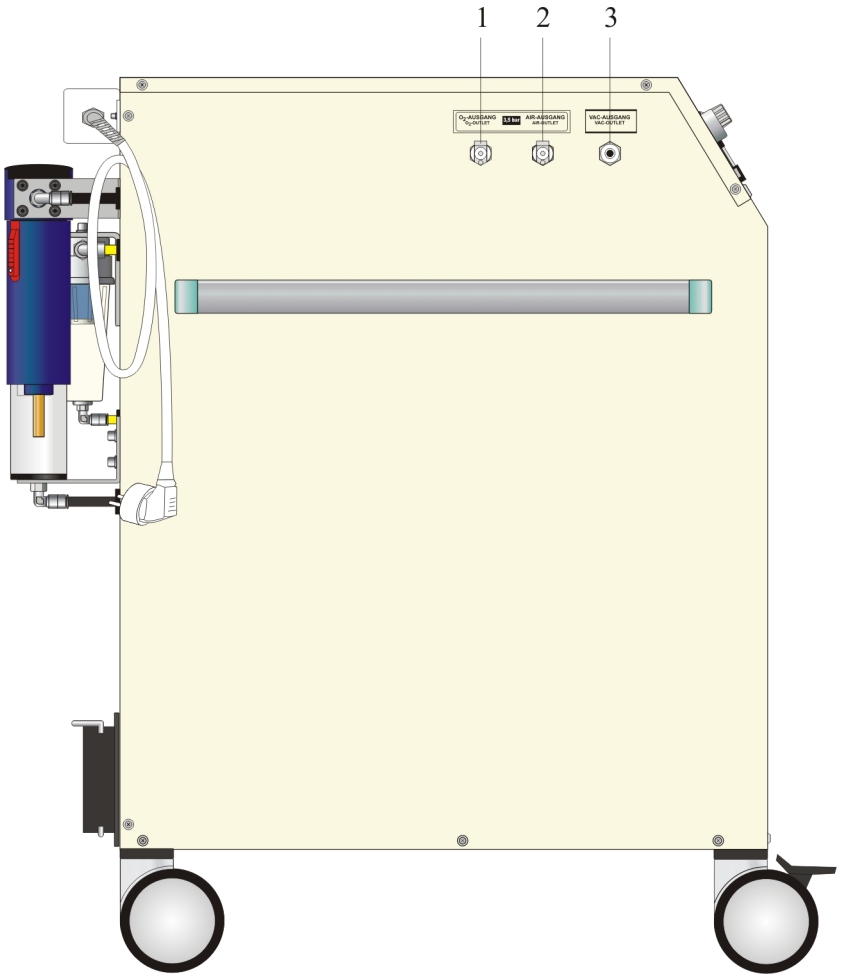

Fig. 5: Left-hand side view

1 O_2 outlet
2 AIR outlet
3 VAC outlet

4 Preparing for operation

4.1 Erecting the device

STAXEL 3.5 with rollers

STAXEL 3.5 is supplied on rollers.

The front rollers of the device are equipped with parking brakes to prevent any unintended movement of **STAXEL 3.5**.

Press lightly on the brake lever to activate the parking brake by blocking the rollers. Lift the brake lever with the tip of your foot to release the parking brake again.

Caution

When moving the device, ensure that the wheel brakes have been released and are applied again when set upright.

Information

STAXEL 3.5 must only be erected and operated in dry, well-ventilated rooms with low dust levels. Moist or wet environments can drastically impair the functioning of the device. Ensure in particular that there are no containers filled with water or similar in the immediate vicinity.

When choosing the site for erecting the device, make sure there is easy access for operation, cleaning and maintenance.

The ambient temperature should never exceed +40° C. For relative humidity levels exceeding 70%, it is advisable to operate the device only in air-conditioned rooms.

The air intake grids on the back of the device must not be covered or any objects placed on them.

There should be spacing of at least 10 cm to the wall at the rear of the device.

4.2 Connecting to the gas and power supply

4.2.1 Gas supply

Check the pressure gauge on the front to see whether there is sufficient pressure. The needle must show more than 3 bar.

Connections for O_2 and AIR

The outlets for O_2 and AIR are on the two sides of **STAXEL 3.5**. The connections are quick-release couplings which lock automatically when connected.

To pull the tube out of the connection, at the same time press the unlocking pin on top of the connection.

Connection for VAC

The outlet for vacuum is on the right of the device. The connection is a 1/8" tube nozzle. Simply insert the tube to the intake unit.

4.2.2 Power supply

STAXEL 3.5 runs on 230 V AC.

1. Connect the mains lead at the rear of the device to the power socket on the wall.
2. Switch on the power switch "On/Off" for O_2 and AIR on the front of the device. The switch lights up green.
3. Switch the power switch "On/Off" for VAC on the front of the device. The switch lights up green.

Electrical accessories

Electrical accessories can be connected to the 4 auxiliary power sockets. The auxiliary power sockets are switched on with the mains switch "On/Off" for O_2 and AIR on the front of the device.

Warning

When in use, **STAXEL 3.5** can only have max. 4 user-accessible auxiliary power sockets.

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Warning

No not connect any further multiple power sockets, e.g. socketa dapters, to the auxiliary power sockets.

Warning

Mains failure also means failure of the auxiliary power sockets,

5 Test list

All relevant tests must be carried out before using the device. The staff carrying out the test must have exact knowledge of the operating manual.

Prerequisites for the test

The device is completely assembled and connected up.

5.1 Test before starting the device every time

Check pressure

- Remove all tubes from the connections
- Visually check the pressure gauge for O_2 and AIR
- All pressure must be in the correct range (> 3 bar).

Check condition of device

- Check the device for any signs of damage
- Check the mains lead and electrical devices for any external signs of damage
- Visually check the LEDs

5.2 Test before every patient

- Check O_2 concentration
- Visually check the pressure gauge for O_2 and AIR

All pressure must be in the correct range (> 3 bar)

Danger

The device must not be used if it fails any of the tests!

6 Operation

6.1 Switching on

Only switch the device on if it is not pressurized!

1. Switch on the mains switch "On/Off" for O_2 and AIR on the front of the device.
2. **STAXEL 3.5** starts to generate oxygen and compressed air
3. The pressure in the corresponding pressure gauges for oxygen and compressed air on the front panel increases to 3.5 bar.
4. Switch on the mains switch "On/Off" for VAC on the front of the device.
5. **STAXEL 3.5** starts to generate vacuum.

6.2 Switching off

1. Switch off the mains switch "On/Off" for O_2 and AIR on the front of the device.
2. Pressure is released from the tanks.
3. Switch off the mains switch "On/Off" for VAC on the front of the device.

6.3 Stopping the device

1. Switch off the mains switch "On/Off" for O_2 and AIR on the front of the device.
2. Pressure is released from the tanks.
3. Switch off the mains switch "On/Off" for VAC on the front of the device.
4. Remove all tubes from the connections.
5. Disconnect the device from the mains.

7 Troubleshooting

Fault	Cause	Remedy
No pressure for O_2 and compressed air, acoustic alarm	▪ No power supply ▪ Fuse defect	▪ Check power supply ▪ Replace fuse
Initial pressure of O_2 or compressed air falls below 2.5 bar, acoustic alarm	▪ Fine filter clogged ▪ Gas consumption too high ▪ Compressor defect ▪ Tube leaks	▪ Replace fine filter ▪ Reduce gas consumption ▪ Inform F. STEPHAN GMBH customer service
Red LED "Visual overheating alarm" (Fig. 2) on, the device stops working	▪ **STAXEL 3.5** overheated ▪ Insufficient air flow to cool the capacitor	▪ Replace filter mat ▪ Check that fan works properly, replace if necessary
Red LED "Visual alarm for failure of electronic component or switching valves« (Fig. 2) is on	▪ Valves not switching correctly ▪ Electronic component defect ▪ Compressor defect ▪ Supply tube torn off	▪ Inform F. STEPHAN GMBH customer service
O_2 concentration falls below minimum value	▪ Balance of pressure between the two absorber tanks no longer balanced ▪ Outdated absorber tanks	▪ Readjust absorber ▪ Flow too high ▪ Replace absorber tanks

Tab. 4: Troubleshooting

8 Care and maintenance

8.1 Disinfection and sterilisation

Caution

As with operation of the device, it must only be cleaned and disinfected by instructed members of staff.

Proceed with routine cleaning at regular intervals according to the local hospital routine.

All disposable parts must be disposed of in an environment-friendly manner according to the local hospital routine.

All instrument and surface disinfectants based on alcohol and aldehyde may be used.

Do not use deoxygenating or dechlorinating disinfectants or disinfectants containing phenol or its derivatives.

Amino derivatives can damage soft plastics (tubes).

Caution

All used disinfectants must be certified in accordance with relevant environmental legislation.

Caution

Always comply with the regulations for handling cleaning agents and disinfectants issued by the Professional Association.

Caution

When using cleaning agents and disinfectants, pay attention to correct concentrations and reaction times as otherwise damage to the materials cannot be ruled out.

Caution

When using effective substances other than those stated, please contact the manufacturer of the disinfectant to obtain compatibility confirmation.

8.1.1 Device housing, gas connections, mains lead

Cleaning

- Wiping disinfection

Procedure

1. Wipe down the surfaces with ready made-up disinfectant solution (surface disinfectant).
2. The cloth should be no more than damp.
3. No moisture must be allowed to penetrate in the device.

8.2 Safety checks

Safety checks are to be carried out every twelve months by the manufacturer or the authorized customer service for F. STEPHAN GMBH.

8.3 Maintenance

For reasons of device safety, it is advisable to proceed with maintenance of **STAXEL 3.5** after every approx. 1000 operating hours but at least every twelve months together with the safety checks.

Maintenance is to be carried out by the authorized customer service for F. STEPHAN GMBH.

After 10,000 operating hours, arrange for a general overhaul to be carried out by the authorized customer service for F. STEPHAN GMBH.

Only use spare parts from F. STEPHAN GMBH for maintenance.

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8.3.1 Filter unit

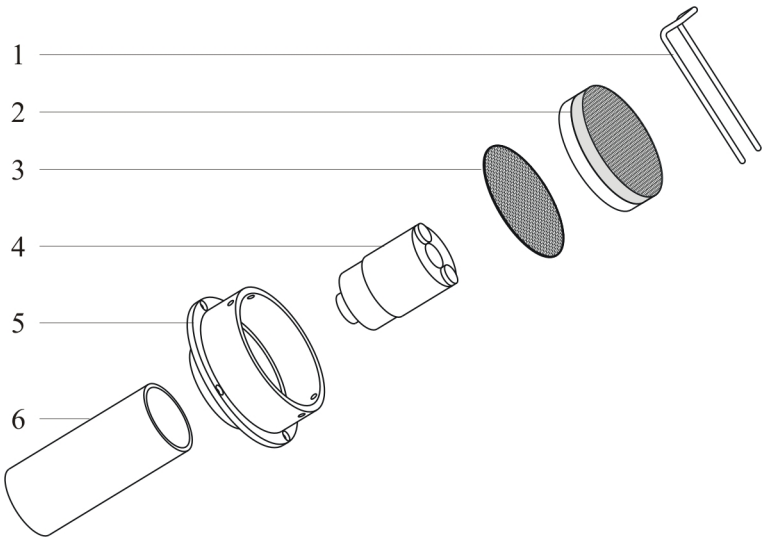

Fig. 6: Exploded drawing intake filter

1	Holder	4	Intake filter
2	3-ply bacteria filter	5	Housing flange
3	Stainless steel fine sieve	6	Tube for housing flange

The bacteria filter for room air must be replaced and the intake filter mat cleaned every 10 days or after every 250 operating hours. Please note that these intervals can be drastically reduced depending on the contamination levels in the ambient air.

At the beginning, please check the condition of the bacteria filter every 2-3 days to reduce the changing intervals if necessary. The bacteria filter must be changed when it goes gray.

Changing the bacteria filter

1. Pull the holder out of the housing flange.
2. Remove the 3-ply bacteria filter and replace with a new bacteria filter (in **STAXEL 3.5** spare parts set).
3. Replace the holder again.

Check the intake filter integrated in the intake filter housing every time after changing the 3-ply bacteria filter. If the bacteria filter is changed too late, the intake filter can become clogged with dust particles so that the air supply to the compressors is drastically reduced. This can result in a rapid fall in the O_2 concentration of **STAXEL 3.5**.

Changing the intake filter

1. Pull the holder out of the housing flange.
2. Remove the 3-ply bacteria filter.
3. Remove the stainless steel fine sieve.
4. Unscrew the intake filter and screw in a new one (in **STAXEL 3.5** spare parts set).
5. Put the stainless steel fine sieve in again.
6. Insert the 3-ply bacteria filter.
7. Put the holder back in again.

The intake filter cannot be cleaned!

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9 List of accessories

Pos.	Designation	Art. No.	Quantity (ea)
1	Fuses 8 A (T)	1 804 60 026	2
2	Fuses 1.25 A (T)	1 804 60 004	2
3	3-ply bacteria ultra-fine filter	1 600 60 115	6
4	Intake filter mat	1 600 61 123	6
5	Intake silencer & bacteria filter	1 600 40 046	6
6	O ring 4.47 x 1.78 EPDM	1 950 60 031	10
7	Filter insert for moisture filter	1 925 60 362	3

Tab. 5: List of accessories

10 Guarantee

The manufacturer F. STEPHAN GMBH grants a 24 month guarantee from the date of purchase.

Any intervention in the device or repairs must only be carried out by F. STEPHAN GMBH or an authorized expert. Otherwise the guarantee becomes null and void.

The guarantee also becomes null and void if the device is handled incorrectly.

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13 Notes

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